REMARKS

Claim Rejections 35 U.S.C. § 112

The Examiner has rejected Claim 20 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states the limitation "the distal port" lacks sufficient antecedent basis. Applicant has amended the claim to correct this deficiency and requests that the Examiner withdraw the rejection.

Claim Rejections 35 U.S.C. § 102

Next, the Examiner rejected Claims 1-2 and 4-10 under 35 USC §102(e) as being anticipated by Freeman et al. (USPN 6,306,114). The Examiner contends that Freeman discloses each limitation of the invention as claimed, including a bioabsorbable plug body and a bioabsorbable sealing member.

Applicant has carefully reviewed the Freeman reference and respectfully submits that it fails to disclose the use of bioabsorbable materials for either the plug body or the sealing member. Indeed, Freeman only discloses that silicone is a preferred material and that other suitable "resilient" materials may be used. In contrast, bioabsorbable materials offer very specific characteristics that must be intentionally chosen. Since there is no explicit teaching regarding the use of a bioabsorbable material, one of skill in the art would not take Freeman's disclosure of "other suitable materials" as a suggestion to use a bioabsorbable material.

Further, Freeman's device is a plug designed to provide long term sealing of the nasal lacrimal duct. It is proposed as an alternative to laser sealing and sutures. As such, the use of a bioabsorbable material would defeat the use of Freeman's device in its intended manner. Accordingly, one of skill in the art would have no motivation to modify Freeman's device by employing bioabsorbable materials.

With respect to Claim 2, Applicant further submits that Freeman provides no teaching regarding the use of a material that is "expandable when exposed to fluid" for the sealing member. Again, the only specific material disclosed by Freeman is silicone. Further, as shown

in Figs. 1-3, 5, 6, 8, 9, 10 and others, the valve material is shown to be a monolithic feature of the plug body, formed from the same material and is described in the specification as being simultaneously formed by injection molding. However, Claim 1 specifically states that the plug body is formed from material that "does not expand when exposed to the fluid" and therefore has different claimed properties. Thus, Freeman fails to disclose these aspects of the invention.

With respect to Claim 4, the Examiner states that the valve of Freeman, element 20a-e corresponds to the sealing member and that it "may be annularly shaped." Applicant respectfully contends that Freeman does not disclose an "annularly shaped" sealing member. The specification of this application uses annular consistently with its most common meaning, that is something ring-like or ring shaped. Applicant has carefully reviewed the Freeman reference and submits that one of skill in the art would not describe any of the valves disclosed as "ring-like." For example, the elements 20a-e cited by the Examiner are either flap type valves having a hinged member that is secured along an edge or slit type valves that comprise a thin membrane having one or more straight cuts. In addition to the flapper valve and slit valve, the only other specific valve disclosed by Freeman is a duckbill valve. Applicant contends that none of these constitute a disclosure of an annularly shaped sealing member.

For the above reasons, Applicant respectfully submits that Freeman et al. fail to disclose all the limitations of the invention recited in Claims 1, 2 and 4-10. Accordingly, Applicant requests that the Examiner reconsider and withdraw § 102(e) rejection of these claims over Freeman.

Claim Rejections 35 U.S.C. § 103

The Examiner has rejected Claim 3 under 35 USC §103(a) as being obvious over Freeman as discussed above, in view of Brucker (USPN 6,296,657). The Examiner contends that Brucker discloses the use of an expanding gel foam for the sealing member.

As discussed above, Applicant contends that Freeman fails to suggest the use of a plug member formed from bioabsorbable materials. One of skill in the art would not use a bioabsorbable material with the Freeman plug since that would run counter to its intended purpose. Similarly, Brucker discloses a device having a surface member 22 that the Examiner

compares to the plug member. Since the surface member 22 is designed to be removed after the wound has healed, there is no reason to use a bioabsorbable material. Further, since the structure is located on the surface of the skin, it would not be subjected to the physiological conditions required to bioabsorb the structure.

For these reasons, Applicant respectfully requests that the Examiner reconsider and withdraw the § 103(a) rejection of Claim 3 over Freeman in view of Brucker.

Next, the Examiner has rejected Claims 11-18 under 35 USC §103(a) as being unpatentable over Freeman as cited above in view of Hermann et al. (U.S.P.N 5,871,474). The Examiner cites Freeman for the teachings discussed above and cites Hermann for its teaching of a tapered lumen and contends that it renders the use of a sealing member comprising a coil of material obvious.

First, Applicant notes that Freeman suffers from the deficiencies discussed above. Primarily, Freeman fails to disclose or suggest that the plug body be formed from a bioabsorbable material. As discussed above, there is no reason for one of skill in the art to use a bioabsorbable material with the Freeman plug since that would run counter to its intended purpose. Similarly, Hermann also fails to suggest the use of a bioabsorbable material. Hermann is directed to a trocar stabilizer having an inflatable seal. As such, the Hermann device is used during endoscopic procedures and there simply no reason for such an apparatus to be formed from bioabsorbable material. Accordingly, neither Freeman nor Hermann disclose or suggest a plug body formed from bioabsorbable material.

Additionally, the Examiner cites Hermann for its teaching of a helical thread on the outside of the apparatus. The Examiner suggests that such screw threads "may take the form of a coil and increase the traction of the sealing member within the body to effectively keep it in place," concluding that it would be obvious to modify Freeman on this basis. Applicant respectfully disagrees with this analysis.

First, the screw threads noted by the Examiner are present on the outer surface of the structure that is analogous to the plug body, not the sealing member. Since the screw threads disclosed by Hermann are on a completely different structure, Applicant submits that this

disclosure is irrelevant to the design of the sealing member. Indeed, Hermann discloses a sealing member that is formed from an inflatable cuff. As such, there is clearly no connection between the screw threads and the sealing member.

Moreover, Applicant's disclosure of the use of a coil of material to form the sealing member depends upon the ability of the coil of material to compress as it moved down the tapered lumen of the plug body, as shown, for example, in Applicant's Figs. 6b and 6d. This corresponds to the claim requirement that "the sealing member being movable into the tapered portion for substantially sealing the lumen from fluid flow therethrough." In contrast, the screw threads provided on the outer surface of the Hermann apparatus have no similar function.

Further, Applicant contends that the Freeman and Hermann combination cited by the Examiner fails to disclose the required characteristics of the sealing member. Claim 11 requires that the sealing member be annularly-shaped and that it be movable into the tapered portion of the lumen to seal the lumen from fluid flow. As discussed above, Applicant respectfully submits that Freeman fails to disclose or suggest an annularly shaped sealing member. For example, the Examiner cites Fig. 5 of Freeman as showing a sealing member that "may be wedged into the tapered portion." Applicant notes that the valve 20a disclosed in Fig. 5 is a duckbill valve that "comprises two resilient flaps 40a, 42a which are biased together." See USPN 6,306,114, col. 4, lines 31-32. Applicant submits that neither this structure nor the other valves structures suggested by Freeman are "annularly shaped" as required by Claim 11.

For the above reasons, Applicant requests that the Examiner reconsider and withdraw the § 103 rejection of Claims 11-18 over Freeman in view of Hermann.

Next, the Examiner rejected Claims 19-20, 22-25, 27-28, 32-35 and 37 under 35 USC §103(a) as being unpatentable over Freeman as cited above in view of Atkinson (USPN 6,645,225). The Examiner supplements the teachings of Freeman discussed above with Atkinson's disclosure of an elongate member lumen in communication with the plug member lumen and a second elongate member comprising a location indicator.

Applicant submits that the combination proposed by the Examiner fails to suggest the use of a plug member formed from a bioabsorbable material. As discussed above, Freeman does not

disclose the use of a bioabsorbable material and one of skill in the art would not be motivated to modify the Freeman plug by using a bioabsorbable material since that would run counter to purpose of the device. Similarly, Atkinson discloses a plug designed to seal a Patent Foramen Ovale (PFO) that exists between chambers of the heart. The purpose of the plug is to permanently seal the opening, so the use of a bioabsorbable material would defeat its function.

Accordingly, since neither reference discloses or suggests the use of a plug member formed from bioabsorbable material, Applicant respectfully requests that the Examiner withdraw the § 103(a) rejection of pending Claims 19-20, 22-25, 27-28, and 32-35.

Next, the Examiner rejected Claims 26, 31 and 36 under 35 USC §103(a) as being unpatentable over Freeman and Atkinson as discussed above, further in view of Sepetka et al. (USPN 5,814,062). The Examiner cites the Sepetka reference for its teaching of an activation element.

As with the above rejections, Applicant notes that the primary references fail to suggest the use of bioabsorbable material. Sepetka similarly fails to disclose or suggest the use of a bioabsorbable material. The structure cited by the Examiner as being analogous to a plug member is coupling 30, which is used in the delivery of implant coil 28. As disclosed by Sepetka, "[t]ubular coupling 30 can be made from platinum, stainless steel or plastic that is biocompatible with the environment in which the coupling will be placed." See USPN 5,814,062 Col. 7, lines 52-55. Accordingly, there is no motivation to employ a bioabsorbable material and since the structures are intended to be permanent, the use of a bioabsorbable material would be inappropriate.

With respect to this rejection, the Examiner states that "Freeman et al. disclose the claimed device, including the elongate member moving the sealing member into a smaller diameter portion of the plug member (Figures 15-16)." Applicant respectfully disagrees with this interpretation of the Freeman reference. The elongate member does not engage the sealing member, but rather the seat 116 of the lumen. As described, valve 110 is biased to the closed direction regardless of the use of elongate member 160, and opens only when a pressure

differential exists across the valve. Accordingly, Applicant submits that Freeman fails to disclose or suggest the elongate member moving the sealing member.

For these reasons, Applicant respectfully requests that the Examiner withdraw the § 103(a) rejection of Claims 26, 31 and 36.

Finally, the Examiner rejected Claim 29 and 30 under 35 USC §103(a) as being unpatentable over Freeman and Atkinson as discussed above, further in view of Davis (USPN 6,143,004) with respect to Claim 29, and further in view of Sommercorn et al. (USPN 6,494,848) with respect to Claim 30. The Examiner cites Davis for its teaching of a bleed back lumen and Summercorn for an expandable member that provides tactile feedback for the location of the distal end of an elongate member.

Again, Applicant submits that the primary references fail to suggest the use of bioabsorbable material. The secondary references Davis and Sommercorn cannot compensate for this deficiency since their teachings do not include any structure that corresponds to the plug member, nor do they provide any relevant teaching regarding the use of bioabsorbable materials. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the § 103(a) rejection of Claims 29 and 30.

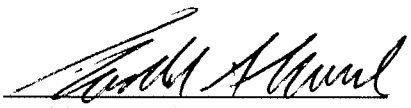
Conclusion

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Examiner is encouraged to call the undersigned collect at (415) 705-6377 if there are any outstanding issues or questions which can be resolved to allow this application to be passed to issue.

Respectfully submitted,

DERGOSITS & NOAH LLP

Date: December 17, 2008

By: 
Todd A. Noah
Reg. No. 35,626